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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,396	05/01/2007	Gerald E. Pierard	BTI 3.3-002 CIP	3608
530 7590 01/05/2011 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER KIM, JENNIFER M	
			ART UNIT 1628	PAPER NUMBER
			MAIL DATE 01/05/2011	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,396	Applicant(s) PIERARD ET AL.	
	Examiner JENNIFER M. KIM	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-13 and 15-28 is/are pending in the application.
- 4a) Of the above claim(s) 7-10, 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 11-13, 15-18 and 23-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/20/2006;11/3/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' election of without traverse of **dry skin or severe dry skin** as a species of non-microbial inflammatory skin condition and **miconazole** as a species of imidazole are acknowledged. Claims 1, 3-6, 11-13, 15-18 and 23-28 have been examined only to the extent of applicants' elected species. Claims 7-10 and 19-22 are withdrawn from consideration since they are non-elected invention.

The amendment filed November 3, 2010 have been received and entered into the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites the limitation "composition" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3-6, 12, and 28 are rejected under 35 U.S.C. 102(a) as being anticipated by Tsuchiya et al. (JP 2003-055186) (see enclosed English Translation).

Tsuchiya et al claimed a humectant comprises of miconazole and its salts as an active principle substance used for a cosmetic constituent for moisturizing the skins. (see claims 1 and 3). Tsuchiya et al teach that the humectant is applied to the skin, such as the scalp, in order to increase the water content at the applied area, thereby providing moisture (page 2 [0001], [0004]). Tsuchiya et al teach that the composition increases the water content in the keratin of the dry scalp and useful for skin dryness (page 5 [0004], page 6). Tsuchiya et al teach that the miconazole nitrate can be formulated in an amount from 0.01 to 5%, preferably in a range of from 0.01 to 3%, and more preferably in a range of from 0.03 to 2%. Tsuchiya et al teach that in the case where the humectant is used as a common humectant for the skin to be incorporated into a cosmetic composition other than the hair cosmetic composition, such as a cosmetic composition for skin, it is generally preferred that the proportion is in a range of from 0.01 to 1% (pages 13-15). This range encompasses and touches Applicants' effective amounts set forth in claims 4 and 5. Tsuchiya et al teach that the formulation has improved dryness with higher efficacy ([0027]- [0029]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 11,13, 15-18 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuchiya et al. (JP 2003-055186) as applied to claims 1, 3-6, 12 and 28 above, and further in view of Clum et al. (U.S.Patent No. 4,911,932) of record.

Tsuchiya et al as applied as before.

Tsuchiya et al lack zinc oxide and petrolatum, and their amounts.

Clum illustrates compositions comprising petrolatum, zinc oxide and miconazole nitrate is useful as a skin care composition for topical application (see examples). The amount of each of the agents in Clum's composition overlaps and encompasses Applicants' amounts set forth in claims.

It would have been obvious to one of ordinary skill in the art to employ Clum's composition comprising miconazole for the treatment of dry skin because miconazole is well known at the time the invention was made as an active principle for the therapeutic benefit in improving skin dryness and because Clum conveniently teaches a skin care composition comprising miconazole for topical application. One would have been motivated to employ Clum's composition having miconazole for the treatment of dry skin in order to achieve an expected therapeutic benefit of miconazole as an active principle in the treatment of dry skin. There is a reasonable expectation of successfully treating dry skin because miconazole is well known at the time the invention was made having therapeutic benefit in treatment of dry skin and as a skin composition for topical application. Therefore, the claimed invention, as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was made, because every

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element of the invention has been collectively taught by the combined teachings of the references.

None of the claims are allowed.

Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1628

Jmk
November 29, 2010